

Notice of Allowability

Application No.

10/600,745

Examiner

Eric S. Olson

Applicant(s)

BARANOWITZ, STEVEN

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address--

All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice of Allowance (PTOL-85) or other appropriate communication will be mailed in due course. **THIS NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIGHTS.** This application is subject to withdrawal from issue at the initiative of the Office or upon petition by the applicant. See 37 CFR 1.313 and MPEP 1308.

1. ☒ This communication is responsive to Applicant's amendment submitted September 15, 2006.
2. ☒ The allowed claim(s) is/are 5 and 8.
3. ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 - a) ☐ All b) ☐ Some* c) ☐ None of the:
 1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

* Certified copies not received: _____.

Applicant has THREE MONTHS FROM THE "MAILING DATE" of this communication to file a reply complying with the requirements noted below. Failure to timely comply will result in ABANDONMENT of this application.

THIS THREE-MONTH PERIOD IS NOT EXTENDABLE.

4. ☐ A SUBSTITUTE OATH OR DECLARATION must be submitted. Note the attached EXAMINER'S AMENDMENT or NOTICE OF INFORMAL PATENT APPLICATION (PTO-152) which gives reason(s) why the oath or declaration is deficient.
 5. ☐ CORRECTED DRAWINGS (as "replacement sheets") must be submitted.
 - (a) ☐ including changes required by the Notice of Draftsperson's Patent Drawing Review (PTO-948) attached
 - 1) ☐ hereto or 2) ☐ to Paper No./Mail Date _____.
 - (b) ☐ including changes required by the attached Examiner's Amendment / Comment or in the Office action of Paper No./Mail Date _____.
- Identifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the drawings in the front (not the back) of each sheet. Replacement sheet(s) should be labeled as such in the header according to 37 CFR 1.121(d).
6. ☐ DEPOSIT OF and/or INFORMATION about the deposit of BIOLOGICAL MATERIAL must be submitted. Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.

Attachment(s)

1. ☐ Notice of References Cited (PTO-892)
2. ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3. ☒ Information Disclosure Statements (PTO/SB/08), Paper No./Mail Date September 1, 2006
4. ☐ Examiner's Comment Regarding Requirement for Deposit of Biological Material
5. ☐ Notice of Informal Patent Application
6. ☒ Interview Summary (PTO-413), Paper No./Mail Date _____
7. ☒ Examiner's Amendment/Comment
8. ☒ Examiner's Statement of Reasons for Allowance
9. ☐ Other _____

SHAOJIA ANNA JIANG, PH.D.
SUPERVISORY PATENT EXAMINER

Detailed Action

This application is a divisional application of 09/856881, filed May 24, 2001, now US patent 6670397, which is a national stage application of PCT/US00/21015, filed July 31, 2000, which claims benefit of provisional applications 60/146272, filed July 29, 1999, and 60/168558, filed December 2, 1999. Applicant's amendment, submitted September 15, 2006, is acknowledged wherein claims 1-4, 6-7, and 9-13 are cancelled and claims 5 and 8 are amended.

Claims 5 and 8 are pending in this application and examined on the merits herein.

The reasons for allowance will be discussed below.

The reasons for allowance and Examiner's amendment are as follows:

Examiner's Amendment

An examiner's amendment to the record appears below. Should the changes and/or additions be unacceptable to applicant, an amendment may be filed as provided by 37 CFR 1.312. To ensure consideration of such an amendment, it MUST be submitted no later than the payment of the issue fee.

The claims are renumbered as follows:

Independent claim 5 is renumbered as claim 1.

Dependant claim 8 is renumbered and amended as follows:

8. 2. The method of claim 5 1, wherein said agent is administered orally.

The **title** of the invention is amended. The new title is as follows:

Methods for regeneration of a mammalian lens

The **abstract** is amended. The new abstract is as follows:

The invention relates to methods for transdifferentiation of body tissues which can be used to generate specific cell types needed for regenerating a lens in the mammalian eye, following loss or removal of the original lens. ~~organs or body parts, following cellular degeneration, injury or amputation. The present invention also describes the use of tissue transdifferentiation for treating cancer and autoimmune diseases.~~

Reasons for Allowance

Currently, claims 1-2, formerly numbered 5 and 8, are pending in this application.

Claims 1-2, formerly numbered 5 and 8,, have been examined on the merits herein.

The claimed method of regenerating a mammalian lens by transdifferentiation, is not seen to be taught or fairly suggested by the prior art, as discussed below.

Applicant's amendments filed September 15, 2006 with respect to the rejection of former claims 2, 3, and 9-11 under 35 USC § 112, second paragraph for lacking antecedent basis in the parent claim, have been fully considered and found to be persuasive to remove the rejection as the rejected claims are no longer pending.

Applicant's amendments filed September 15, 2006 with respect to the rejection of former claims 1-11 and 13 under 35 USC § 112, first paragraph for lacking enablement for the regeneration of tissues other than the lens, have been fully considered and found to be persuasive to remove the rejection as the claims as amended no longer read on a method of regeneration of tissues other than the lens.

Applicant's amendments filed September 15, 2006 with respect to the rejection of former claims 9 and 10 under 35 USC § 102(b), for being anticipated by Gerber et al.,

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have been fully considered and found to be persuasive to remove the rejection as the rejected claims are no longer pending.

Applicant's amendments filed September 15, 2006 with respect to the rejection of former claims 9 and 11 under 35 USC § 102(b), for being anticipated by Kulkarni et al., have been fully considered and found to be persuasive to remove the rejection as the rejected claims are no longer pending.

Applicant's amendments filed September 15, 2006 with respect to the rejection of former claims 2 and 5-8 under 35 USC § 103, for being anticipated by Kulkarni et al. in view of Gerber et al., have been fully considered and found to be persuasive to remove the rejection as the amended claims are drawn to a method of regenerating a lens, which is not obvious over the cited references, and no longer includes within its scope a method of promoting wound healing in the skin as described by Kulkarni et al. in view of Gerber et al.

The terminal disclaimer filed on October 12, 2006, disclaiming the terminal portion of any patent granted on this application which would extend beyond the expiration date of US patent 6670397 has been reviewed and is accepted. The terminal disclaimer has been recorded.

The terminal disclaimer, filed on October 12, 2006 with respect to the potential rejection of claims 5 and 8 under the judicially created doctrine of obviousness-type

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double patenting as being unpatentable over claims 1-9 of US patent 6670397, has been considered and found to be persuasive. Therefore this rejection is not made.

Reasons for allowance are as follows: The claimed method of regenerating a mammalian lens is seen to be novel and non-obvious over the prior art and is directed to subject matter adequately described and enabled by Applicant's specification. For example, written description and enablement are provided by the *in vivo* method and experimental data disclosed on pp. 18-22 of Applicant's specification as example 1. One skilled in the art would be able to practice the claimed invention without performing undue experimentation. It is not known in the prior art to successfully induce regeneration of the lens in a gerbil or other mammal after loss or removal of the original lens. The closest prior art to the claimed invention are the methods of promoting wound healing in a mammal described previously as being disclosed by Gerber et al. and Kulkarni et al. The claimed invention is directed to a different tissue or organ, in this case, the lens, than that of the cited references, which both concern injury of the skin. Therefore the indicated subject matter is allowable over the prior art

Accordingly, Applicant's amendment submitted September 15, 2006, and the accompanying examiner's amendment, are sufficient to remove all rejections made in the prior office action as discussed above and to place the application in condition for allowance.

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Any comments considered necessary by Applicant must be submitted no later than the payment of the issue fee and, to avoid processing delays, should preferably accompany the issue fee. Such submissions should be clearly labeled, "Comments on Statement of Reasons for Allowance."

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Eric S. Olson whose telephone number is 571-272-9051. The examiner can normally be reached on Monday-Friday, 8:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Shaojia Anna Jiang can be reached on (571)272-0627. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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Eric Olson



Patent Examiner

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9/19/06

Anna Jiang



Supervisory Patent Examiner

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